REPORT NUMBER FIFTY-ONE

to the

Secretary

U.S. Department of Health and Human Services

(Re: Physicians Regulatory Issues Team, Drug Competitive Acquisition Program, Contractor Reform, Physician Fee Schedule, Physician Education on the Prescription Drug Benefit, Pay for Performance Initiatives, and other matters)

From the

Practicing Physicians Advisory Council

(PPAC)

Hubert H. Humphrey Building

Washington, DC

March 7, 2005

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SUMMARY OF THE MARCH 7, 2005, MEETING

Agenda Item A — Introduction

The Practicing Physicians Advisory Council (PPAC) met at the Department of Health and Human Services' Hubert H. Humphrey Building in Washington, D.C., on Monday, March 7, 2005 (see Appendix A). The chair, Ronald Castellanos, M.D., welcomed the members of the Council to the 51st meeting of PPAC. Dr. Castellanos explained that the previous chair, Michael T. Rapp, M.D., resigned from the Council to take a position with CMS' Office of Clinical Standards and Quality. Dr. Castellanos thanked Dr. Rapp for his excellent work leading the Council and said he is pleased that CMS is adding more practicing physicians to its staff.

Agenda Item B — Welcome

Herb Kuhn, Director of the Center for Medicare Management, also thanked Dr. Rapp for his service. He said his staff is working to get background information about agenda items to the Council members as early as possible and also to structure the agenda to allow sufficient time for discussion of concerns.

OLD BUSINESS

Agenda Item C — Update: November 22, 2004, Recommendations and Old Business

Ken Simon, M.D., M.B.A., Executive Director of PPAC, presented the responses from CMS to PPAC recommendations made at the November 22, 2004, meeting (Report Number 50, Appendix 1).

> 50-C-1: PPAC recommends that CMS format the presentation of PPAC recommendations and responses similar to the format used by the Physicians Regulatory Issues Team (PRIT) and that the recommendations and responses be made available to PPAC members before each PPAC meeting.
>
> **CMS Response**: CMS will make every effort to respond to the Council's recommendation(s) by the subsequent meeting date. Once the responses are completed, reviewed, and cleared by the Agency, CMS will make them available to the Council members.
>
> 50-D-1: PPAC applauds CMS for approving additional funding for all carriers who requested funding of part-time staff to clear the backlog in physician enrollment applications.
>
> **CMS Response**: The new enrollment backlog, which peaked at 45,712 in April 2004, was below 20,000 as of January 27, 2005. Re-assignments peaked at 44,667 in April 2004 and had dropped below 11,000 as of January 21, 2005, which is below the historic norm of 13,365 calculated in December 2004.

50-F-1: PPAC recommends that CMS specifically identify all the data sources it uses for determining professional liability relative value updates.

CMS Response: CMS used specialty-specific malpractice premium data for the top 20 Medicare physician specialties measured by total payments. Premiums were for a $1 million/$3 million mature claims-made policy (a policy covering claims made, rather than services provided during the policy term). CMS attempted to collect 2000 and 2001 premium data from all 50 states, Washington, D.C., and Puerto Rico. Data were collected from commercial and physician-owned insurers and from joint underwriting associations.

The premium data collected from the private insurance companies had to "match" the market share data provided by the respective State Departments of Insurance. Because none of the State Departments of Insurance had 2003 market share information at the time of data collection, 2003 premium data were not usable.

50-F-2: PPAC recommends that CMS institute a process to receive information from physicians from all specialties if they are unable to purchase drugs at average sales price (ASP), as well as a process to institute changes in the ASP before the end of the quarter and to make those changes retroactive to the beginning of the quarter.

CMS Response: Physicians should work with their specialty societies to identify drug suppliers with optimal prices. For example, the American Society of Clinical Oncology (ASCO) has committed to working with its membership on this issue. A recent ASCO survey of drug acquisition costs indicated that lower prices were not necessarily dependent on practice size. The group is identifying the purchasing strategies of these smaller practices. CMS expects other specialty societies are similarly committed to helping their membership on this issue.

While CMS receives data from individual drug manufacturers on ASPs, it is prohibited by law from disclosing these data at the national drug code level. The law requires that the Medicare payment be based on the ASP plus 6%. On the issue of mid-quarter changes, the law requires quarterly reporting and price updates.

50-F-3: PPAC recommends that CMS discontinue the least costly alternative policies, as they do not comply with Congress' and CMS' expressed desire to let market forces determine ASP.

CMS Response: Least costly alternative policies are local coverage determinations (LCDs). These policies follow the public process associated with all LCDs and are based on clinical evidence. If physicians in a local area believe that the clinical evidence on which an LCD is based is no longer valid, CMS

encourages active dialogue between the local carrier and the local physicians on the evidence.

50-F-4: PPAC recommends that CMS investigate carriers' poor application of least costly alternative policies.

CMS Response: CMS is continually monitoring carriers' performance of all their responsibilities. While one carrier did experience a claims processing issue surrounding an LCD involving a least costly alternative policy, the carrier has corrected the problem. CMS is unaware of any current claims processing issues surrounding LCDs involving least costly alternative policies.

50-F-5: Because CMS has already compiled a list of drug prices by manufacturer to determine ASP, PPAC recommends the list be published on the CMS website so physicians can use the information to purchase drugs under ASP.

CMS Response: Due to the proprietary nature of the ASP data, the law prohibits its disclosure at the level recommended by PPAC.

50-F-6: PPAC recommends that CMS and the Office of the Actuary compare and contrast the factors in the Medicare Economic Index (MEI) and the market basket to explain why the same index cannot be used for both physicians and hospitals.

CMS Response: Section 1842(b)(3) of the Act details the requirements of the MEI, specifically stating that it be developed "…on the basis of appropriate economic index data, that such higher level is justified by year-to-year economic changes." The MEI, both as it is currently defined and in prior versions, reflects the cost structure and price changes associated with the inputs used in providing *physician* services.

Section 1886(b)(3)(iii) of the Act requires the development of a hospital market basket that is "… based on an index of appropriately weighted indicators of changes in wages and prices which are representative of the mix of goods and services included in such inpatient hospital services…." The hospital market basket, therefore, reflects the cost structure and price changes associated with the inputs used in providing *hospital* services covered under the inpatient hospital prospective payment system.

As such, CMS and the Office of the Actuary feel it would be inconsistent with the legislative requirement, as well as technically inappropriate, for the MEI and the hospital market basket to be defined similarly.

50-F-7: PPAC recommends that CMS expand the criteria for participation in the 1-year demonstration project on cancer treatment to include among the types of

chemotherapy subcutaneous and intramuscular infusion, intravesical application, and surgical implants, in addition to push and infusion methods.

CMS Response: The 1-year demonstration project is a limited-scope study designed to evaluate the impacts of monitoring patients' symptoms related to chemotherapy administered through push or infusion. CMS believes the 1-year cancer demonstration project is a valuable experiment in improving the quality of cancer care provided to Medicare beneficiaries. However, CMS thinks it is premature to discuss expanding the scope of the demonstration project until it has adequately evaluated the current project data. By limiting the study to the methods of chemotherapy administration selected, CMS is better able to control for other factors that may affect these symptoms (e.g., longer infusion times associated with implanted pumps).

50-G-1: PPAC recommends that Medicare provide to physicians a MedLearn Matters article simplifying the concepts of observation vs. inpatient admissions to improve physicians' practices in admitting patients to hospitals.

CMS Response: CMS is currently reviewing several issues related to physician orders and patient status in a hospital setting. Once these issues are resolved, CMS will develop a MedLearn Matters article that summarizes Medicare policy related to observation status and patient admission.

50-I-1: PPAC requests that the Doctors Office Quality-Improvement Information Technology (DOQ-IT) Project work with the Office of the Inspector General or general counsel to find measures that can legally protect physicians when information is gathered under quality improvement activities.

CMS Response: Patient information contained in an electronic health record and submitted to the Quality Improvement Organization would not be discoverable in malpractice actions. By law, such information is already protected from discovery in such actions.

50-I-2: PPAC requests DOQ-IT provide guidance for levels of security required to avoid infractions under the Health Insurance Portability and Accountability Act (HIPAA).

CMS Response: To ensure compliance with the Privacy Rule when using medical records, providers must merely ensure that they "reasonably safeguard protected health information from any intentional or unintentional use or disclosure that is in violation of the standards, implementation specifications of other requirements of this subpart." See 45 CFR 164.530(a)(2).

From the Security Rule perspective, covered entities are required to ensure the confidentiality, integrity, and availability of all electronic protected health

information (ePHI) the entity creates, receives, maintains, or transmits. Covered entities must protect against reasonably anticipated threats or hazards to the security or integrity of this information, as well as against reasonably anticipated, but impermissible, uses and disclosures of the ePHI. The Security Rule was written with the recognition that each covered entity is unique and varies in size and resources. Consequently, to achieve these requirements, a covered entity may use security measures that are reasonable and appropriate in its environment, taking into account its size, complexity, capabilities, the costs of security measures, and the probability and criticality of potential risks to its ePHI.

The Department of Health and Human Services recently issued additional guidance on the Security Rule; it can be found at the following Internet address: www.cms.hhs.gov/hipaa/hipaa2/education/Security%20101_Cleared.pdf
Copies are available (Appendix 2).

50-J-1: PPAC recommends CMS pursue multiple avenues to educate beneficiaries new to Part B Medicare about the "Welcome to Medicare" exam benefit and its limitations and rules.

CMS Response: CMS has developed and is continuing to develop external communications/collaborations to make beneficiaries aware of the new preventive benefit. These include information in the *Medicare & You 2005* handbook, the revised booklet, *Guide to Medicare's Preventive Services*, multiple fact sheets (including one that will be translated into 14 languages), a bilingual brochure for Hispanic beneficiaries, use of various community-based outreach and education programs, and many other means of educating the public through CMS websites, the toll-free helpline 1-800-MEDICARE, regional offices, State Health Insurance Assistance Programs (SHIPs), and partners at the national, state, and local levels. CMS is also working on an outreach toolkit to be used in 2005 in public/town hall meetings by members of Congress that will include messages on the new preventive benefits. Local promotional materials, including public service announcements, drop-in articles, and flyers, are also available at this time.

In addition, the Provider Communications Group provider education and outreach strategy ensures that physicians and other health professionals are informed about the new preventive benefits and are prepared to assist Medicare beneficiaries in obtaining new services, such as an initial preventive physical examination, cardiovascular screening, and diabetes screening. The Agency believes that the provider community plays a key role in helping CMS ensure that all eligible beneficiaries receive these services when appropriate.

Staff also attend cross-agency meetings and conferences of provider organizations and professional associations to ensure coordination, consistency of content and language, and incorporation of core messages into beneficiary-related information.

50-O-1: PPAC recommends that CMS provide the discussion materials for agenda items at least 3 weeks prior to the PPAC meeting to allow for preparation and self-education by PPAC members.

CMS Response: CMS recognizes the importance of the Council members having access to the discussion materials as early as possible to be prepared to provide appropriate input relative to issues and policy decisions. CMS is committed to providing the agenda and the discussion materials in as prompt and timely a manner as possible.

The Council thanked Dr. Simon for his report. The Council requested that a more detailed comparison of the components that make up the Physician Fee Schedule and the hospital payment systems be provided at a future meeting.

NEW BUSINESS

Agenda Item D — Update PRIT

William Rogers, M.D., Director of PRIT and Medical Officer to the Administrator, said CMS is working with the American Medical Association's (AMA's) Current Procedural Terminology (CPT) Editorial Board to distinguish between two methods of chemotherapy administration (push and infusion) in terms of the need for the continuous presence and supervision (Appendix 3). Other new issues under evaluation or recently addressed by PRIT include billing for use of a first assistant in hospitals that have surgical training programs, the Recovery Audit Contracts demonstration, the competitive acquisition program (CAP) for oncology drugs beginning in 2006, electronic payment for daptomycin, revision of the reimbursement amount for endometrial cryoablation (CPT 58356), and denials of reimbursement for Pap tests.

Agenda Item F — Competitive Bidding on Drugs

Don Thompson, Director of Outpatient Services for the Center for Medicare Management, said the current proposal for the CAP separates drugs into categories according to their use by specialty (Appendix 4). Vendors would be required to provide all the drugs commonly furnished by a given specialty (e.g., oncologists, urologists). Physicians would have the option of purchasing through the vendors or negotiating prices independently but would not be able to do both. From the physician's standpoint, the claims process would remain the same. The proposal also includes a drug tracking system to verify that physicians received and administered the drugs purchased.

51-F-1: PPAC recommends that CMS require vendors selected through the CAP to absorb the cost of returned drugs or of unusable drugs and that vendors be willing to advance credit for drugs to patients who are not able to pay the copay.

51-F-2: PPAC recommends that CMS require vendors selected through the CAP be willing to provide drugs for off-label use when evidence supports such use; in such cases, vendors may use the established CMS process for determining medical necessity.

51-F-3: PPAC recommends that CMS allow individual practicing physicians to select, on a drug-by-drug basis, whether to purchase drugs from vendors participating in the CAP program.

51-F-4: PPAC recommends to CMS that prices set by vendors selected through the CAP process not affect the ASP for those who purchase drugs outside of the CAP program.

51-F-5: PPAC recommends that CMS help affected providers find sources of affordable drugs, and that CMS report to PPAC some mechanism to accomplish this goal, which was recommended by the Government Accountability Office.

Deleted: Accounting

Agenda Item G — Medicare Contracting Reform

Thomas Gustafson, Ph.D., Deputy Director of the Center for Medicare Management, explained that contractor reform is intended to improve communication, coordination, responsiveness, efficiency, and accountability (Appendix 5). Part A and Part B contractors would combine into single units, Medicare Administrative Contractors (MACs, also called Primary A/B MACs). CMS proposes establishing 15 distinct geographic Primary A/B MACs to serve the whole country, plus Specialty MACs divided into four geographic areas (for durable medical equipment and home health/hospice care). The law allows 6 years for CMS to transition to the new system. The Primary A/B MACs would be the single point of contact for most issues, from claims payment to system problems.

51-G-1: PPAC recommends to CMS that any money used for incentives to MACs be derived from new funds or administrative savings and not from the Physician Fee Schedule.

51-G-2: PPAC recommends that CMS continue the Carrier Advisory Committee program.

51-G-3: PPAC recommends that CMS maintain the accessibility of carrier medical directors' offices to providers, even if that requires adding staff positions.

51-G-4: PPAC recommends that, as part of contractor reform, CMS develop more integration of Parts A and B, even if new legislation is required, to allow funds to follow services from Part A to Part B.

51-G-5: PPAC recommends that CMS look into combining the Primary A/B MACs, the durable medical equipment MACs, and the home health/hospice MACs into a single jurisdiction in the future.

51-G-6: PPAC recommends that CMS move toward more web-enabled access for provider-based services to improve services at both the front end and the back end.

51-G-7: PPAC recommends that CMS include in MAC contracts a mechanism by which physicians can evaluate the service provided by contractors and use the results of that evaluation to determine improvement plans or discontinuing contracts.

Agenda Item J — Physician Fee Schedule, 2006 Proposed Rule

Steve Phillips, Director of Practitioner Services for CMS, said the Agency identified 171 high-volume CPT codes for specialties that had not recently been reviewed and referred that list to the AMA's Relative Value Update Committee (RUC) for 5-year review (Appendix 6). The Agency received comments from 25 specialty societies asking that evaluation and management (E&M) codes be reviewed because the work dynamics of typical E&M visits have changed. The American College of Cardiology and the American College of Radiology submitted supplemental survey data for calculation of practice expenses.

51-J-1: PPAC recommends that CMS begin projecting the effect on Medicare beneficiaries' access to physician care if the proposed decrease in the Physician Fee Schedule as a result of the Sustainable Growth Rate comes to pass and that CMS develop a plan to prevent decreases in physician participation.

51-J-2: PPAC recommends that CMS use its administrative authority to remove Medicare-covered physician-administered drugs and biologics from the physician payment formula retroactive to 1996.

Agenda Item K — Medicare Prescription Drug Benefit: CMS's Physician Education Plan

Robin Fritter, Technical Advisor, and Suzanne Lewis, Health Insurance Specialist, both from the Provider Communications Group for the Division of Provider Information Planning and Development, described CMS's efforts to inform physicians about the 2006 drug benefit plan so that physicians can direct beneficiaries to sources of information (Appendix 7). They explained that a different office is responsible for educating beneficiaries but said physicians would be notified and briefed about information sent to beneficiaries. Council members suggested some additional avenues for reaching physicians but stressed that CMS must make it easier for beneficiaries to get clear, comprehensive information without consulting their physicians.

Agenda Item M — Pay for Performance Initiatives

Trent Haywood, M.D., Acting Deputy Director and Chief Medical Officer of the Office of Clinical Standards and Quality, cited multiple sources emphasizing the need to improve the quality of medical care (Appendix 8). He described the complex issues involved in designing quality improvement initiatives and performance incentives and outlined some current CMS demonstration projects. Council members identified numerous areas still to be addressed, such as unintended consequences, information technology issues, and establishing quality criteria.

> 51-M-1: PPAC recommends that as CMS develops and implements pay for performance programs, these programs should remain in alignment with certain principles and guidelines developed by the AMA and attached to the AMA written statements (Appendix 9).
>
> 51-M-2: PPAC recommends that CMS ensure that implementation of any quality improvement/pay for performance program is premised on establishment of a reliable, positive Medicare physician payment formula.
>
> 51-M-3: PPAC recommends that, as part of the pay for performance program, CMS develop criteria for electronic medical records and data collection sets to facilitate dissemination of information technology to physician practices.

Agenda Item N — Testimony

The Council reviewed written testimony provided by the AMA (Appendix 9) and the Alliance of Specialty Medicine (Appendix 10).

Agenda Item O — Wrap Up and Recommendations

The Council reviewed the recommendations. The Council asked that CMS staff present information about the Recovery Audits Contract demonstration at a future meeting. Dr. Castellanos adjourned the meeting at 4 p.m. Recommendations of the Council are listed in Appendix B.

Report prepared and submitted by
Dana Trevas, Rapporteur

PPAC Members at the March 7, 2005, Meeting

Ronald Castellanos, M.D., *Chair*
Urologist
Cape Coral, Florida

Jose Azocar, M.D.
Internist
Springfield, Massachusetts

Peter Grimm, D.O.
Radiation Oncologist
Seattle, Washington

Carlos Hamilton, Jr., M.D.
Endocrinologist
Houston, Texas

Joe W. Johnson, D.C.
Chiropractor
Paxton, Florida

Barbara L. McAneny, M.D.
Clinical Oncologist
Albuquerque, New Mexico

Geraldine O'Shea, D.O.
Internist
Jackson, California

Laura Powers, M.D.
Neurologist
Knoxville, Tennessee

Michael T. Rapp, M.D., J.D.
Emergency Room Physician
Arlington, Virginia

Anthony Senagore, M.D.
Surgeon
Cleveland, Ohio

Robert Urata, M.D.
Family Practitioner
Juneau, Alaska

CMS Staff Present:

David C. Clark, RPH, Director
Office of Professional Relations
Center for Medicare Management

Robin Fritter, Technical Advisor
Provider Communications Group
Division of Provider Information Planning and Development
Center for Medicare Management

Dr. Thomas Gustafson, Deputy Director
Center for Medicare Management

Trent Haywood, M.D., Acting Deputy Director, Chief Medical Officer
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services

Mr. Herb Kuhn, Director
Center for Medicare Management

Suzanne Lewis, Health Insurance Specialist
Provider Communications Group
Division of Provider Information Planning and Development
Center for Medicare Management

Mr. Steve Phillips, Director
Division of Practitioner Services
Center for Medicare Management

Dr. William Rogers, Director
Physicians Regulatory Issues Team
Medical Officer to the Administrator
Centers for Medicare and Medicaid Services

Dr. Ken Simon, Executive Director, PPAC
Center for Medicare Management

Mr. Don Thompson, Director
Division of Outpatient Services
Center for Medicare Management

Public Witnesses:

None

Dana Trevas, Rapporteur

APPENDICES

Appendix A: Meeting agenda
Appendix B: Recommendations from the March 7, 2005, meeting

The following documents were presented at the PPAC meeting on March 7, 2005, and are appended here for the record:

Appendix 1: Practicing Physicians Advisory Council Update
Appendix 2: HIPAA Security Series: Security 101 for Covered Entities
Appendix 3: PRIT Report
Appendix 4: Part B Drug Competitive Acquisition Program, 2006 Proposed Rule
Appendix 5: Medicare Contracting Reform
Appendix 6: Physician Fee Schedule, 2006 Proposed Rule
Appendix 7: Medicare Prescription Drug Coverage Provider Education and Outreach Strategy
Appendix 8: Strategies Today for Superior Health Care Tomorrow
Appendix 9: Written Statement of the American Medical Association to the Practicing Physicians Advisory Council
Appendix 10: Written Statement of the Alliance of Specialty Medicine to the Practicing Physicians Advisory Council

Appendix A

Practicing Physicians Advisory Council
Hubert H. Humphrey Building
Room 705A
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201
March 7, 2005

8:30 – 8:40 a.m.	**A. Open Meeting**	**Ronald Castellanos, M.D.** **Chairman** **Practicing Physicians Advisory Council**
8:40 – 8:50 a.m.	**B. Welcome**	**Herb Kuhn** **Director** **Tom Gustafson, Ph.D.** **Deputy Director** **Center for Medicare Management** **Centers for Medicare & Medicaid Services**
8:50 – 9:15 a.m.	**C. Update**	**Kenneth Simon, M.D., M.B.A.** **Executive Director** **Practicing Physicians Advisory Council**
9:15-9:45 a.m.	**D. PRIT Update**	**William Rogers, M.D.** **Director** **Physicians Regulatory Issues Team** **Office of Public Affairs** **Centers for Medicare and Medicaid Services**
9:45 – 10 a.m.	**E. Break (Chair Discretion)**	

10 – 11:00 a.m.	**F. Competitive bidding on drugs**	**Don Thompson Director Division of Outpatient Services Center for Medicare Management**
11- 12 NOON	**G. Report to Congress on Contractor Reform**	**Tom Gustafson Deputy Director Center for Medicare Management**
NOON – 1:15 p.m.	**H. Lunch**	
1:40- 2:00 p.m.	**J. Physician Fee Schedule Rule**	**Steve Phillips Director Physician Practitioner Services Centers for Medicare & Medicaid Services**
2:00- 2:45 p.m.	**K. Medicare Prescription Drug Benefit: CMS' physician education plan**	**Robin Fritter Technical Advisor Provider Communications Group Division of Provider Information Planning and Development Center for Medicare Management** **Suzanne Lewis Health Insurance Specialist Provider Communications Group Division of Provider Information Planning and Development Center for Medicare Management**

2:45- 3:00 p.m.	**L. Break (Chair discretion)**	
3:00 –3:45 p.m.	**M. Pay for Performance Initiatives**	**Trent Haywood, M.D. Acting Deputy Chief Medical Officer Office of Clinical Standards & Quality Centers for Medicare and Medicaid Services**
3:45- 4:15 p.m.	**N. Testimony**	
4:15–4:45 p.m.	**O. Wrap Up/Recommendations**	**Herb Kuhn Director Thomas Gustafson, Ph.D. Deputy Director Center for Medicare Management Centers for Medicare & Medicaid Services**

**** Subject to change***

Appendix B

PRACTICING PHYSICIANS ADVISORY COUNCIL (PPAC) RECOMMENDATIONS
Report Number Fifty-One
March 7, 2005

Agenda Item F — Competitive Bidding on Drugs

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